June 21, 2001

FDA,

I am writing to try to impress upon you the urgency of getting Lotronex back on the market and soon. I would like to see Lotronex come back for "compassionate use" or under an Open Label Safety Study until this issue can be resolved.

Since the withdrawal of Lotronex in November, there are many people suffering needlessly, and I am one of them.

I am aware that GSK and the FDA are working towards a solution, but it seems to be taking a very long time to get resolved. I know there are currently many issues that need to be worked through, but again, there are many people who are suffering. Lotronex has really worked for me and I would like to see it back on the market and available to those who really benefited from the drug. Since there is currently no other effective drug for IBS, (I've tried them all!) it is very important to many people that Lotronex be brought back. There are many of us who really need to this drug to live a "normal" life.

I urge you to please get this drug reinstated and soon so many of us can stop suffering! IBS is not a serious disease, but it is VERY DIBAILITING!

Regards,

Marilyn Schuller

41800 Wild Turkey Lane

Canton, MI 48188

marilyn\_schuller@hp.com

734-397-1377

018-0169

C16



Marilyn Schuller 41800 Wild Turkey Ln. Canton, MI 48188-2085



Ասիկիուկոնդինությանության ա



FDA \*\*
Dockets Management Branch
5630 Fishers Lane
Room 1061 HFA-305
Rockville, MD 20852

Docket # 01P-0169